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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,953	06/17/2002	Anthony Douglas Shannon	28594/38247	2556

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EXAMINER

HILL, MYRON G

ART UNIT PAPER NUMBER

1648

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/049,953

Applicant(s)

SHANNON ET AL.

Examiner

Myron G. Hill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21 and 23-50 is/are pending in the application.
- 4a) Of the above claim(s) 32-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21 and 23-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/22/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to the paper filed March 15, 2006.

Claims 21 and 23-31 are under consideration in the action.

Information Disclosure Statement

A signed and initialed copy of the IDS paper filed June 22, 2006 is enclosed.

Claim Rejections Withdrawn

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 21 and 22-31 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant pointed to support and the rejection is withdrawn.

Claim Rejections - 35 USC § 103

Claims 21, 23, 24 and 29-31 were rejected under 35 U.S.C. 103(a) as being anticipated by Srivastava (WO 99/29834, from IDS).

Applicant's arguments were persuasive and the rejection is withdrawn.

Claims 21 and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Srivastava and Deregt *et al.* (1998 Virus Res Vol 57, pages 171-181).

Applicant's arguments were persuasive and the rejection is withdrawn.

Rejections Maintained

Claim Rejections - 35 USC § 112

Claims 21 and 22-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what the term "non-mammalian heat shock response" means and it is not clear the metes and bounds of the stimulus that causes it.

Applicant argues that the term is defined in the specification and points to the use of non-mammalian cells.

Applicant's arguments have been fully considered and not found persuasive.

Applicant points to the use of non-mammalian cells and not to something that defines the term from any heat shock response. It is not clear what the difference is between "non-mammalian" heat shock response and other heat shock responses.

The term remains unclear.

New Rejections Necessitated By IDS

Claim Rejections - 35 USC § 103

Claims 21, 23-26 and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roman *et al.* (Immunology 1996 Vol 88 page 487-492, from IDS).

The claims are drawn to a method of producing an immunogenic complex comprising a step wherein the cell has been subjected to a stimulus that causes induction of heat shock response.

Roman *et al.* teach that immunogenic peptides bound to hsp70 are efficient in priming T-cell responses (page 487, column 2, last part paragraph).

One of ordinary skill in the art would have known that proteins could be expressed in *E. coli* and insect cells with baculovirus and that both of these cells have heat shock proteins. One of ordinary skill in the art would have been motivated to stimulate the heat shock response to induce the production of hsp in cells expressing the antigen of interest to save time and steps in order not to have to purify both hsp and antigen and mix them *in vitro*.

Thus, it would be *prima facie* obvious to modify the method of Roman *et al.* to make the immunogenic composition with the expectation of success.

Claims 21 and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roman *et al.* and Deregt *et al.* (1998 Virus Res Vol 57, pages 171-181).

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The claims are drawn to a method of producing an immunogenic complex comprising a step wherein the cell has been subjected to a stimulus that causes induction of heat shock response.

Roman *et al.* is discussed above and teaches making immunogenic complexes with heat shock proteins.

Roman *et al.* does not teach BVDV as the heterologous antigenic peptide.

Deregt *et al.* teach that BVDV is a known pathogen of bovines and that the E2 region has been used as a subunit vaccine (page 172, column 1, second full paragraph).

One of ordinary skill in the art would have been motivated to make the antigenic hsp complexes of Roman *et al.* to make other immunogenic formulations because Roman *et al.* teaches that the made compositions give rise to immune responses.

One of ordinary skill in the art would have been motivated to use BVDV because it is known that it is a common virus and has economic implications because of the disease it causes.

Thus, it would be *prima facie* obvious to make the immunogenic complex of Roman *et al.* with the antigen of Deregt *et al.* with the expectation of success in making the complex to BVDV.

Conclusion

No claim is allowed.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 22 June 2006 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Myron G. Hill
Patent Examiner
21 August 2006



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